Complete Summary

GUIDELINE TITLE

Irritable bowel syndrome in adults. Diagnosis and management of irritable bowel syndrome in primary care.

BIBLIOGRAPHIC SOURCE(S)

National Collaborating Centre for Nursing and Supportive Care. Irritable bowel syndrome in adults. Diagnosis and management of irritable bowel syndrome in primary care. London (UK): National Institute for Health and Clinical Excellence (NICE); 2008 Feb. 27 p. (Clinical guideline; no. 61).

GUIDELINE STATUS

This is the current release of the guideline.

COMPLETE SUMMARY CONTENT

SCOPE

DISEASE/CONDITION(S)

Irritable bowel syndrome (IBS)

GUIDELINE CATEGORY

Diagnosis
Evaluation
Management
Treatment

CLINICAL SPECIALTY

Family Practice
Gastroenterology
Internal Medicine
Psychology

INTENDED USERS

Dietitians
Patients
Physicians
Psychologists/Non-physician Behavioral Health Clinicians

GUIDELINE OBJECTIVE(S)

- To provide positive diagnostic criteria for people presenting with symptoms suggestive of irritable bowel syndrome (IBS)
- To provide guidance on clinical and cost-effective management of IBS in primary care
- To determine clinical indications for referral to IBS services, taking into account cost effectiveness

TARGET POPULATION

Adults (18 years and older) who present to primary care with symptoms suggestive of irritable bowel syndrome (IBS)

Note: This guideline does not cover:

- People with other gastrointestinal disorders such as non-ulcer dyspepsia or coeliac disease
- Children and young people under 18 years
- Inflammatory bowel disease

INTERVENTIONS AND PRACTICES CONSIDERED

Diagnosis

1. Initial assessment
    - Evaluation of symptoms
    - Physical examination, including examination for "red flag" indicators
    - Referral to secondary care
2. Diagnostic tests
    - Full blood count (FBC)
    - Erythrocyte sedimentation rate (ESR) or plasma viscosity
    - C-reactive protein (CRP)
    - Antibody testing for coeliac disease (endomysial antibodies [EMA] or tissue transglutaminase [TTG])

Note: The following tests were considered, but were not recommended to confirm diagnosis: ultrasound, rigid/flexible sigmoidoscopy, colonoscopy, barium enema, thyroid function test, faecal ova and parasite test, faecal occult blood test, hydrogen breath test.

Management

1. Dietary and lifestyle advice
2. Pharmacological therapy
    - Antispasmodic agents
    - Laxatives
    - Loperamide
    - Tricyclic antidepressants (TCAs)
    - Selective serotonin reuptake inhibitors (SSRIs)
3. Referral for psychological interventions
    - Cognitive behavioural therapy (CBT)
    - Hypnotherapy
    - Psychological therapy
4. Complementary and alternative medicine (CAM), including acupuncture and reflexology (considered, but not recommended)
5. Follow-up

MAJOR OUTCOMES CONSIDERED

- Symptomatic improvement
- Quality of life
- Adverse effects

METHODOLOGY

METHODS USED TO COLLECT/SELECT EVIDENCE

Hand-searches of Published Literature (Primary Sources)
Searches of Electronic Databases

DESCRIPTION OF METHODS USED TO COLLECT/SELECT THE EVIDENCE

Note from the National Guideline Clearinghouse (NGC): This guideline was developed by the National Collaborating Centre for Nursing and Supportive Care (NCC-NSC) on behalf of the National Institute for Health and Clinical Excellence (NICE). See the "Availability of Companion Documents" field for the full version of this guidance.

Clinical Effectiveness Review Methods

Search Strategy

The search strategies and the databases searched are presented in detail in Appendix B in the full version of the original guideline document (see the "Availability of Companion Documents" field). All searches were carried out on the following core databases: Medline, Embase, Cinahl (all using the OVID interface) and The Cochrane Library. Additional databases were searched for individual reviews where appropriate.

For this guideline, a general set of terms was produced relating to irritable bowel syndrome (IBS). The relevance of the terms diarrhoea and constipation was explored before they were included in the IBS filter. For each review, terms related to the intervention were combined with the set of IBS terms. Where

appropriate, study design filters (randomised controlled trial [RCT] and systematic review) were applied. Results were limited to papers published in English where possible. All searches were updated to June 2007.

Hand-searching was not undertaken following NICE advice that exhaustive searching on every guideline review topic is not practical or efficient. Reference lists of articles were checked for studies of potential relevance.

Methods of the Review

Sifting Process

Once the search had been completed, the following sifting process took place:

- 1st sift: one reviewer sifted the title/abstract for articles that potentially met the eligibility criteria
- 2nd sift: full papers were ordered that appeared relevant and eligible or where relevance/eligibility was not clear from the abstract
- 3rd sift: full papers were appraised, generally by one reviewer using an inclusion criteria form, and this was checked where necessary by a second reviewer.

Quality Assessment and Validity

Once individual papers were retrieved, the articles were checked for methodological rigour (using quality checklists appropriate for each study design), applicability to the United Kingdom (UK) and clinical significance. Assessment of study quality concentrated on dimensions of internal validity and external validity. At this stage, some studies were excluded if the interventions were not licensed for use in the UK or they were not regularly used in the UK. Studies in which the interventions were obsolete were also excluded.

Studies for which the methodological quality indicated a high potential for bias were included in the review, but were not included in the analysis.

Cost Effectiveness Review Methods

Objectives of Cost-Effectiveness Review

1. To determine the cost-effectiveness of tests to identify alternative diagnoses in patients meeting the diagnostic criteria for IBS who do not have any "red-flag" symptoms.
2. To assess the cost-effectiveness of interventions used in the management of IBS.

Search Strategy for Identification of Studies

Searches were performed on the MEDLINE database for objective 1 using the strategy given in appendix B in the full version of the original guideline document. Specific searches were also performed on the National Health Service economic evaluation database (NHS EED) database using the Medical Subject Heading

(MeSH) terms for inflammatory bowel disease (exploded to include Crohn's disease and ulcerative colitis), lactose intolerance and coeliac disease. Free-text searching on the NHS EED database was explored but did not yield any further relevant papers.

Searches were performed on the MEDLINE database for objective 2 using the strategy in Appendix B of the full version of the original guideline document. Specific searches were also performed on the NHS EED database using the MeSH term for irritable bowel syndrome which yielded two further papers. Free-text searching on the NHS EED database was explored but did not yield any further relevant papers.

NUMBER OF SOURCE DOCUMENTS

Not stated

METHODS USED TO ASSESS THE QUALITY AND STRENGTH OF THE EVIDENCE

Expert Consensus
Weighting According to a Rating Scheme (Scheme Given)

RATING SCHEME FOR THE STRENGTH OF THE EVIDENCE

Grading Evidence

For some reviews, the Guideline Development Group used the GRADE scheme to assess the quality of the evidence for each outcome using the approach described below, and evidence summaries across all outcomes were produced)

According to the GRADE scheme, evidence is classified as high, moderate, low or very low:

- High - further research is very unlikely to change the confidence in the estimate of effect
- Moderate - further research is likely to have an important impact on the confidence in the estimate of effect and may change the estimate
- Low - further research is very likely to have an important impact on the confidence in the estimate of effect and is likely to change the estimate
- Very low - any estimate of effect is very uncertain

The procedure adopted when using GRADE was:

1. A quality rating was assigned, based on the study design – for example, randomised controlled trials (RCTs) started as high and observational studies as low.
2. This rating was up or downgraded according to specified criteria: study quality, consistency, directness, preciseness and reporting bias. These criteria are detailed in the full version of the guideline document (see the "Availability of Companion Documents" field). Criteria were given a downgrade mark of -1 or -2 depending on the severity of the limitations.

3. The downgrade/upgrade marks were then summed and the quality rating revised. For example, a decrease of -2 points for an RCT would result in a rating of 'low'.
4. Wherever possible, reasoning was explained for the downgrade marks.

METHODS USED TO ANALYZE THE EVIDENCE

Meta-Analysis of Randomized Controlled Trials
Systematic Review with Evidence Tables

DESCRIPTION OF THE METHODS USED TO ANALYZE THE EVIDENCE

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Data Abstraction

Data from the included studies were extracted by one reviewer for each review, with random checking by a second reviewer, and entered into a Microsoft Access relational database that had been especially designed for the guideline. The use of the database provided a more structured extraction, for example, only certain choices could be made for some items, although free text fields were also used. The main advantage of using a database for this purpose is that a large amount of detail can be input, and then an overview obtained using database sorting procedures. The following data were extracted from each study:

- Review being addressed
- Study details: study design (RCT, quasi-randomised, cohort study, etc); parallel/crossover, washout period; country where trial conducted; setting; funding
- Study quality
- Participants: age (mean and range), gender (ratio male:female), co-morbidities, inclusion/exclusion criteria, IBS diagnosis method, type of IBS, presence of bloating, presence of pain, measure of severity of IBS, symptom status at trial entry, length of time since diagnosis, duration of symptoms, ethnicity, socio-economic group, weight, postinfective/non post-infective initiated IBS
- Interventions: class (e.g. insoluble fibre) and sub-class (e.g. wheat bran), total amount per day, frequency/time of consumption, means of delivery (oral capsule, taken as a food, drink, etc), duration of treatment; concurrent treatment in both arms
- Comparator: placebo (details of what it is), other control group, other intervention
- Outcome: including follow-up period, scales used, definition of success (if using "improved", "complete response", etc)
- Results for each outcome

Appraisal of Methodological Quality

The methodological quality of each trial was assessed by one reviewer and randomly checked by a second. See section 5.2 in the full version of the original guideline document (see "Availability of Companion Documents" field) for a list of quality items that were assessed.

Data Synthesis

Meta-analysis of similar trials, where appropriate, was carried out using The Cochrane Collaboration's analysis software, Review Manager (Version 4.2). Trials were pooled using a fixed effects model and plotted on forest plots. Where there was significant heterogeneity, a random effects model was used as a sensitivity analysis.

For dichotomous studies, reviewers used the analyses reported by the authors, which was usually those reporting an outcome. Where there were incomplete data reported (more than 20% missing in any one group), reviewers carried out sensitivity analyses, excluding these studies.

Where it was possible to combine studies, outcomes were summarised for dichotomous data using odds ratios (as default), relative risks (where the event rate in either arm was greater than 20%), or Peto odds ratios (where there were studies with no events in one arm). Numbers needed to treat (with the control group rate to which they apply) were calculated from the risk difference, where appropriate. The number needed to treat (NNT) is the number of people who would have to be treated for one to have an improved outcome.

Refer to section 5.2 of the full version of the original guideline document (see the "Availability of Companion Documents" field) for additional information.

METHODS USED TO FORMULATE THE RECOMMENDATIONS

Expert Consensus (Nominal Group Technique)

DESCRIPTION OF METHODS USED TO FORMULATE THE RECOMMENDATIONS

Note from the National Guideline Clearinghouse (NGC): This guideline was developed by the National Collaborating Centre for Nursing and Supportive Care (NCC-NSC) on behalf of the National Institute for Health and Clinical Excellence (NICE). See the "Availability of Companion Documents" field for the full version of this guidance.

Formulating Recommendations and Determining Key Recommendations

Evidence to Recommendations

Each review summarises the evidence, and the guideline development group (GDG) are asked to interpret the evidence before drafting recommendations. In each case, this includes a consideration of the clinical and cost effectiveness evidence; an indication of the factors the GDG took into account, including the balance between benefits and harms; the GDG's reasoning and conclusions, and,

where relevant, the level of agreement amongst the group. This is reported in each individual review section of the full guideline document (see the "Availability of Companion Documents" field), illustrating the relationship between published clinical and cost effective evidence and recommendations for clinical practice.

Key Recommendations

Process

The GDG was asked to vote on key recommendations by secret email ballot using an Excel spreadsheet. This incorporated the full list of recommendations and votes were allocated to the group, in order to try and determine the key priorities for the guideline. Developing consensus through validated instruments is key to ensure that the final list of up to ten key recommendations fully reflect the group as a whole. This enables all constituent members of the group to have equal weighting of opinion as their opinion moves towards a consensus group position. Typically, nominal group technique (NGT) works well for small groups, with 12 to 15 people widely acknowledged in the literature as the maximum number of people involved in this process.

See section 5.5 in the full guideline document to see the results of voting.

Summary

The NGT worked well in developing consensus opinion, reflected by the key recommendations emergent from the process. The nine key recommendations represent the heart of the full guideline and full guideline recommendations. They articulate the evidence supporting the key areas of healthcare practice that will be shaped by the guideline, providing the possibility with effective implementation for people with irritable bowel syndrome (IBS) symptoms being properly diagnosed and managed within primary care.

RATING SCHEME FOR THE STRENGTH OF THE RECOMMENDATIONS

Not applicable

COST ANALYSIS

Cost Effectiveness Review Methods

Whilst cost-effectiveness is an important consideration for all recommendations made within the guideline, two areas were identified as being priority areas for which cost-effectiveness evidence would have particular importance for informing recommendations. These were identified by the health economist in conjunction with the Guideline Development Group (GDG) after consideration of the importance of each clinical question in terms of the number of patients likely to be affected and the impact on costs and health outcomes for those patients.

The use of tests to exclude alternative diagnoses in people with IBS-like symptoms was considered to be a high priority area for economic evaluation for the following reasons: diagnostic testing has the potential to result in earlier

diagnosis of organic disease which may improve health outcomes; the widespread use of tests may have significant cost implications; the use of tests may result in unnecessary anxiety for patients, particularly if the rate of false positive results is high; invasive tests may have adverse consequences for patients in terms of complications.

The use of pharmacological and behavioural interventions in the management of IBS was also identified as a high priority area for economic evaluation. Pharmacological interventions were identified as an area of high priority because the ongoing use of these interventions in a large number of IBS patients would have significant implications for the use of NHS resources. Behavioural interventions were identified as an area of high priority because these are not widely used at present in the management of IBS and therefore significant additional resources may be required if these are recommended for widespread use.

Two approaches were employed to provide cost-effectiveness evidence for the GDG to consider when making recommendations. Firstly, a review of the health economic literature was carried out and relevant health economic evidence was presented to the GDG. Secondly, further economic analysis was carried out in the priority areas where there was insufficient evidence available from the published literature to inform recommendations and where there was sufficient evidence to demonstrate the clinical effectiveness for the intervention or diagnostic strategy. This further economic analysis was conducted in the form of a cost-effectiveness analysis where the additional benefits were measured in terms of quality-adjusted life-years (QALYs) and the additional costs were assessed from an NHS and personal social services perspective. The GDG considered the incremental cost per QALY for alternative management and diagnostic strategies alongside the clinical effectiveness evidence when formulating recommendations. Where one clinical strategy was clearly more effective and less costly than another it was considered cost-effective. Where one strategy was more effective but also more costly, the incremental cost per QALY was estimated and this was compared to a cost effectiveness threshold of 20,000 to 30,000 pounds sterling per QALY in line with the principals laid out in the NICE Guidelines Manual (NICE 2007). For those clinical questions not prioritised for economic analysis, the GDG considered the likely cost-effectiveness of associated recommendations by making a qualitative judgement on the likely balance of costs, health benefits and any potential harms.

See Section 5.3 in the full version of the original guideline document for methods and results of the cost-effectiveness review.

METHOD OF GUIDELINE VALIDATION

External Peer Review
Internal Peer Review

DESCRIPTION OF METHOD OF GUIDELINE VALIDATION

The guideline was validated through two consultations.

1. The first draft of the guideline (the full guideline, National Institute for Clinical Excellence (NICE) guideline and Quick Reference Guide) were consulted with

Stakeholders and comments were considered by the Guideline Development Group (GDG)
2. The final consultation draft of the Full guideline, the NICE guideline and the Information for the Public were submitted to stakeholders for final comments.

The final draft was submitted to the Guideline Review Panel for review prior to publication.

RECOMMENDATIONS

MAJOR RECOMMENDATIONS

Note from the National Guideline Clearinghouse (NGC): This guideline was developed by the National Collaborating Centre for Nursing and Supportive Care (NCC-NSC) on behalf of the National Institute for Health and Clinical Excellence (NICE). See the "Availability of Companion Documents" field for the full version of this guidance.

Diagnosis of Irritable Bowel Syndrome (IBS)

Confirming a diagnosis of IBS is a crucial part of this guideline. The primary aim should be to establish the person's symptom profile, with abdominal pain or discomfort being a key symptom. It is also necessary to establish the quantity and quality of the pain or discomfort, and to identify its site (which can be anywhere in the abdomen) and whether this varies. This distinguishes IBS from cancer-related pain, which typically has a fixed site.

When establishing bowel habit, showing people the Bristol Stool Form Scale (see appendix D of the original guideline document) may help them with description, particularly when determining quality and quantity of stool. People presenting with IBS symptoms commonly report incomplete evacuation/rectal hypersensitivity, as well as urgency, which is increased in diarrhoea-predominant IBS. About 20% of people experiencing faecal incontinence disclose their incontinence only if asked. People who present with symptoms of IBS should be asked open questions to establish the presence of such symptoms (for example, 'tell me about how your symptoms affect aspects of your daily life, such as leaving the house'). Healthcare professionals should be sensitive to the cultural, ethnic and communication needs of people for whom English is not a first language or who may have cognitive and/or behavioural problems or disabilities. These factors should be taken into consideration to facilitate effective consultation.

Initial Assessment

- Healthcare professionals should consider assessment for IBS if the person reports having had any of the following symptoms for at least 6 months:
    - **A**bdominal pain or discomfort
    - **B**loating
    - **C**hange in bowel habit
- All people presenting with possible IBS symptoms should be asked if they have any of the following 'red flag' indicators and should be referred to secondary care for further investigation if any are present (see the NGC

summary of the NICE guideline Referral guidelines for suspected cancer, for detailed referral criteria where cancer is suspected):

  - Unintentional and unexplained weight loss
  - Rectal bleeding
  - A family history of bowel or ovarian cancer
  - A change in bowel habit to looser and/or more frequent stools persisting for more than 6 weeks in a person aged over 60 years

- All people presenting with possible IBS symptoms should be assessed and clinically examined for the following 'red flag' indicators and should be referred to secondary care for further investigation if any are present (see the NGC summary of the NICE guideline Referral guidelines for suspected cancer, for detailed referral criteria where cancer is suspected):
  - Anaemia
  - Abdominal masses
  - Rectal masses
  - Inflammatory markers for inflammatory bowel disease

  If there is significant concern that symptoms may suggest ovarian cancer, a pelvic examination should also be considered.

- A diagnosis of IBS should be considered only if the person has abdominal pain or discomfort that is either relieved by defaecation or associated with altered bowel frequency or stool form. This should be accompanied by at least two of the following four symptoms:
  - Altered stool passage (straining, urgency, incomplete evacuation)
  - Abdominal bloating (more common in women than men), distension, tension or hardness
  - Symptoms made worse by eating
  - Passage of mucus

  Other features such as lethargy, nausea, backache and bladder symptoms are common in people with IBS, and may be used to support the diagnosis.

Diagnostic Tests

- In people who meet the IBS diagnostic criteria, the following tests should be undertaken to exclude other diagnoses:
  - Full blood count (FBC)
  - Erythrocyte sedimentation rate (ESR) or plasma viscosity
  - C-reactive protein (CRP)
  - Antibody testing for coeliac disease (endomysial antibodies [EMA] or tissue transglutaminase [TTG])
- The following tests are not necessary to confirm diagnosis in people who meet the IBS diagnostic criteria:
  - Ultrasound
  - Rigid/flexible sigmoidoscopy
  - Colonoscopy; barium enema
  - Thyroid function test
  - Faecal ova and parasite test
  - Faecal occult blood
  - Hydrogen breath test (for lactose intolerance and bacterial overgrowth)

Clinical Management of IBS

Dietary and Lifestyle Advice

- People with IBS should be given information that explains the importance of self-help in effectively managing their IBS. This should include information on general lifestyle, physical activity, diet and symptom-targeted medication.
- Healthcare professionals should encourage people with IBS to identify and make the most of their available leisure time and to create relaxation time.
- Healthcare professionals should assess the physical activity levels of people with IBS, ideally using the General Practice Physical Activity Questionnaire (GPPAQ; see appendix J of the full version of the guideline [see the "Availability of Companion Documents" field]). People with low activity levels should be given brief advice and counselling to encourage them to increase their activity levels.
- Diet and nutrition should be assessed for people with IBS and the following general advice given.
    - Have regular meals and take time to eat.
    - Avoid missing meals or leaving long gaps between eating.
    - Drink at least eight cups of fluid per day, especially water or other non-caffeinated drinks, for example herbal teas.
    - Restrict tea and coffee to three cups per day.
    - Reduce intake of alcohol and fizzy drinks.
    - It may be helpful to limit intake of high-fibre food (such as wholemeal or high-fibre flour and breads, cereals high in bran, and whole grains such as brown rice).
    - Reduce intake of 'resistant starch' (starch that resists digestion in the small intestine and reaches the colon intact), which is often found in processed or re-cooked foods.
    - Limit fresh fruit to three portions per day (a portion should be approximately 80 g).
    - People with diarrhoea should avoid sorbitol, an artificial sweetener found in sugar-free sweets (including chewing gum) and drinks, and in some diabetic and slimming products.
    - People with wind and bloating may find it helpful to eat oats (such as oat-based breakfast cereal or porridge) and linseeds (up to one tablespoon per day).
- Healthcare professionals should review the fibre intake of people with IBS, adjusting (usually reducing) it while monitoring the effect on symptoms. People with IBS should be discouraged from eating insoluble fibre (for example, bran). If an increase in dietary fibre is advised, it should be soluble fibre such as ispaghula powder or foods high in soluble fibre (for example, oats).
- People with IBS who choose to try probiotics should be advised to take the product for at least 4 weeks while monitoring the effect. Probiotics should be taken at the dose recommended by the manufacturer.
- Healthcare professionals should discourage the use of aloe vera in the treatment of IBS.
- If diet continues to be considered a major factor in a person's symptoms and they are following general lifestyle/dietary advice, they should be referred to a dietitian for advice and treatment, including single food avoidance and exclusion diets. Such advice should only be given by a dietitian.

Pharmacological Therapy

Decisions about pharmacological management should be based on the nature and severity of symptoms. The recommendations made below assume that the choice of single or combination medication is determined by the predominant symptom(s).

- Healthcare professionals should consider prescribing antispasmodic agents for people with IBS. These should be taken as required, alongside dietary and lifestyle advice.
- Laxatives should be considered for the treatment of constipation in people with IBS, but people should be discouraged from taking lactulose.
- Loperamide should be the first choice of antimotility agent for diarrhoea in people with IBS.*

  *__Note__: In certain situations the daily dose of loperamide required may exceed 16 mg, which at the time of publication (February 2008) was an out of licence dose. Informed consent should be obtained and documented.

- People with IBS should be advised how to adjust their doses of laxative or antimotility agent according to the clinical response. The dose should be titrated according to stool consistency, with the aim of achieving a soft, well-formed stool (corresponding to Bristol Stool Form Scale type 4).
- Healthcare professionals should consider tricyclic antidepressants (TCAs) as second-line treatment for people with IBS if laxatives, loperamide or antispasmodics have not helped. TCAs are primarily used for treatment of depression but are only recommended here for their analgesic effect. Treatment should be started at a low dose (5–10 mg equivalent of amitriptyline), which should be taken once at night and reviewed regularly. The dose may be increased, but does not usually need to exceed 30 mg.**

  **__Note__: At the time of publication (February 2008) TCAs did not have UK marketing authorisation for the indications described. Informed consent should be obtained and documented.

- Selective serotonin reuptake inhibitors (SSRIs) should be considered for people with IBS only if TCAs have been shown to be ineffective.***

  ***__Note__: At the time of publication (February 2008) SSRIs did not have UK marketing authorisation for the indication described. Informed consent should be obtained and documented.

- Healthcare professionals should take into account the possible side effects when prescribing TCAs or SSRIs. After prescribing either of these drugs for the first time at low doses for the treatment of pain or discomfort in IBS, the person should be followed up after 4 weeks and then at 6–12 monthly intervals thereafter.

Psychological Interventions

- Referral for psychological interventions (cognitive behavioural therapy [CBT], hypnotherapy and/or psychological therapy) should be considered for people with IBS who do not respond to pharmacological treatments after 12 months and who develop a continuing symptom profile (described as refractory IBS).

Complementary and Alternative Medicine (CAM)

- The use of acupuncture should not be encouraged for the treatment of IBS.
- The use of reflexology should not be encouraged for the treatment of IBS.

Follow-Up

- Follow-up should be agreed between the healthcare professional and the person with IBS, based on the response of the person's symptoms to interventions. This should form part of the annual patient review. The emergence of any 'red flag' symptoms during management and follow-up should prompt further investigation and/or referral to secondary care.

CLINICAL ALGORITHM(S)

An algorithm for diagnosis and management of irritable bowel syndrome (IBS) is provided in the original guideline document.

EVIDENCE SUPPORTING THE RECOMMENDATIONS

TYPE OF EVIDENCE SUPPORTING THE RECOMMENDATIONS

Recommendations are based on clinical and cost effectiveness evidence, and where this is insufficient, the Guideline Development Group (GDG) used all available information sources and experience to make consensus recommendations using nominal group technique.

BENEFITS/HARMS OF IMPLEMENTING THE GUIDELINE RECOMMENDATIONS

POTENTIAL BENEFITS

Effective diagnosis and management of irritable bowel syndrome (IBS)

POTENTIAL HARMS

Adverse effects of medications

QUALIFYING STATEMENTS

QUALIFYING STATEMENTS

- This guidance represents the view of the Institute, which was arrived at after careful consideration of the evidence available. Healthcare professionals are expected to take it fully into account when exercising their clinical judgement. The guidance does not, however, override the individual responsibility of healthcare professionals to make decisions appropriate to the circumstances of the individual patient, in consultation with the patient and/or guardian or carer and informed by the summary of product characteristics of any drugs they are considering.

- As with any clinical practice guideline, the recommendations contained in this guideline may not be appropriate in all circumstances. A limitation of a guideline is that it simplifies clinical decision-making. Decisions to adopt any particular recommendations must be made by practitioners in the context of:
    - Available resources
    - Local services, policies and protocols
    - The circumstances and wishes of the patient
    - Available personnel and devices
    - Clinical experience of the practitioner
    - Knowledge of more recent research findings

IMPLEMENTATION OF THE GUIDELINE

DESCRIPTION OF IMPLEMENTATION STRATEGY

The Healthcare Commission assesses the performance of National Health Service (NHS) organisations in meeting core and developmental standards set by the Department of Health in 'Standards for better health', issued in July 2004. Implementation of clinical guidelines forms part of the developmental standard D2. Core standard C5 says that national agreed guidance should be taken into account when NHS organisations are planning and delivering care.

The National Institute for Health and Clinical Excellence (NICE) has developed tools to help organisations implement this guidance. These are available on the NICE Web site (www.nice.org.uk/CG061; see also the "Availability of Companion Documents" field).

Key Priorities for Implementation

Initial Assessment

- Healthcare professionals should consider assessment for irritable bowel syndrome (IBS) if the person reports having had any of the following symptoms for at least 6 months:
    - Abdominal pain or discomfort
    - Bloating
    - Change in bowel habit
- All people presenting with possible IBS symptoms should be asked if they have any of the following 'red flag' indicators and should be referred to secondary care for further investigation if any are present:*
    - Unintentional and unexplained weight loss
    - Rectal bleeding
    - A family history of bowel or ovarian cancer
    - A change in bowel habit to looser and/or more frequent stools persisting for more than 6 weeks in a person aged over 60 years
- All people presenting with possible IBS symptoms should be assessed and clinically examined for the following 'red flag' indicators and should be referred to secondary care for further investigation if any are present:*
    - Anaemia
    - Abdominal masses
    - Rectal masses

- Inflammatory markers for inflammatory bowel disease

If there is significant concern that symptoms may suggest ovarian cancer, a pelvic examination should also be considered.

- A diagnosis of IBS should be considered only if the person has abdominal pain or discomfort that is either relieved by defaecation or associated with altered bowel frequency or stool form. This should be accompanied by at least two of the following four symptoms:
    - Altered stool passage (straining, urgency, incomplete evacuation)
    - Abdominal bloating (more common in women than men), distension, tension or hardness
    - Symptoms made worse by eating
    - Passage of mucus

  Other features such as lethargy, nausea, backache and bladder symptoms are common in people with IBS, and may be used to support the diagnosis.

Diagnostic Tests

- In people who meet the IBS diagnostic criteria, the following tests should be undertaken to exclude other diagnoses:
    - Full blood count (FBC)
    - Erythrocyte sedimentation rate (ESR) or plasma viscosity
    - C-reactive protein (CRP)
    - Antibody testing for coeliac disease (endomysial antibodies [EMA] or tissue transglutaminase [TTG])
- The following tests are not necessary to confirm diagnosis in people who meet the IBS diagnostic criteria:
    - Ultrasound
    - Rigid/flexible sigmoidoscopy
    - Colonoscopy; barium enema
    - Thyroid function test
    - Faecal ova and parasite test
    - Faecal occult blood
    - Hydrogen breath test (for lactose intolerance and bacterial overgrowth)

Dietary and Lifestyle Advice

- People with IBS should be given information that explains the importance of self-help in effectively managing their IBS. This should include information on general lifestyle, physical activity, diet and symptom-targeted medication.
- Healthcare professionals should review the fibre intake of people with IBS, adjusting (usually reducing) it while monitoring the effect on symptoms. People with IBS should be discouraged from eating insoluble fibre (for example, bran). If an increase in dietary fibre is advised, it should be soluble fibre such as ispaghula powder or foods high in soluble fibre (for example, oats).

Pharmacological Therapy

- People with IBS should be advised how to adjust their doses of laxative or antimotility agent according to the clinical response. The dose should be titrated according to stool consistency, with the aim of achieving a soft, well-formed stool (corresponding to Bristol Stool Form Scale type 4).
- Healthcare professionals should consider tricyclic antidepressants (TCAs)** as second-line treatment for people with IBS if laxatives, loperamide or antispasmodics have not helped. TCAs are primarily used for treatment of depression but are only recommended here for their analgesic effect. Treatment should be started at a low dose (5–10 mg equivalent of amitriptyline), which should be taken once at night and reviewed regularly. The dose may be increased, but does not usually need to exceed 30 mg.

* See 'the NGC summary of the NICE guideline Referral guidelines for suspected cancer, for detailed referral criteria where cancer is suspected.

** At the time of publication (February 2008) TCAs did not have UK marketing authorisation for the indication described. Informed consent should be obtained and documented.

IMPLEMENTATION TOOLS

Audit Criteria/Indicators
Clinical Algorithm
Foreign Language Translations
Patient Resources
Quick Reference Guides/Physician Guides
Resources
Slide Presentation

For information about availability, see the "Availability of Companion Documents" and "Patient Resources" fields below.

INSTITUTE OF MEDICINE (IOM) NATIONAL HEALTHCARE QUALITY REPORT CATEGORIES

IOM CARE NEED

Living with Illness
Staying Healthy

IOM DOMAIN

Effectiveness
Patient-centeredness

IDENTIFYING INFORMATION AND AVAILABILITY

BIBLIOGRAPHIC SOURCE(S)

National Collaborating Centre for Nursing and Supportive Care. Irritable bowel syndrome in adults. Diagnosis and management of irritable bowel syndrome in

primary care. London (UK): National Institute for Health and Clinical Excellence (NICE); 2008 Feb. 27 p. (Clinical guideline; no. 61).

ADAPTATION

Not applicable: The guideline was not adapted from another source.

DATE RELEASED

2008 Feb

GUIDELINE DEVELOPER(S)

National Collaborating Centre for Nursing and Supportive Care - National Government Agency [Non-U.S.]

SOURCE(S) OF FUNDING

National Institute for Health and Clinical Excellence (NICE)

GUIDELINE COMMITTEE

Guideline Development Group

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FINANCIAL DISCLOSURES/CONFLICTS OF INTEREST

All members of the Guideline Development Group (GDG) were required to make formal declarations of interest at the outset, and these were updated at every subsequent meeting throughout the development process. This information is

recorded in the meeting minutes and kept on file at the National Collaborating Centre for Nursing and Supportive Care (NCC-NSC). The GDG declarations are recorded in Appendix K of the full version of the original guideline document.

GUIDELINE STATUS

This is the current release of the guideline.

GUIDELINE AVAILABILITY

Electronic copies: Available in Portable Document Format (PDF) format from the National Institute for Health and Clinical Excellence (NICE) Web site.

AVAILABILITY OF COMPANION DOCUMENTS

The following are available:

- Irritable bowel syndrome in adults: diagnosis and management of irritable bowel syndrome in primary care. Clinical practice guideline. Full guideline. 2008 Feb. 554 p. Electronic copies: Available in Portable Document Format (PDF) from the National Institute for Health and Clinical Excellence (NICE) Web site.
- Irritable bowel syndrome in adults. Diagnosis and management of irritable bowel syndrome in primary care. Quick reference guide. London (UK): National Institute for Health and Clinical Excellence; 2008 Feb. 9 p. (Clinical guideline; no. 61). Electronic copies: Available in Portable Document Format (PDF) from the NICE Web site.
- Irritable bowel syndrome. Appendices to full version. London (UK): National Institute for Health and Clinical Excellence; 2008 Feb. 9 p. (Clinical guideline; no. 61). Electronic copies: Available in Portable Document Format (PDF) from the NICE Web site.
- Irritable bowel syndrome. Costing template. London (UK): National Institute for Health and Clinical Excellence; 2008 Feb. Various p. (Clinical guideline; no. 61). Electronic copies: Available in Portable Document Format (PDF) from the NICE Web site.
- Irritable bowel syndrome. Costing report. London (UK): National Institute for Health and Clinical Excellence; 2008 Feb. 39 p. (Clinical guideline; no. 61). Electronic copies: Available in Portable Document Format (PDF) from the NICE Web site.
- Irritable bowel syndrome in adults. Slide set. London (UK): National Institute for Health and Clinical Excellence; 2008. 16 p. (Clinical guideline; no. 61). Electronic copies: Available in Portable Document Format (PDF) from the NICE Web site.
- Irritable bowel syndrome in adults: diagnosis and management of irritable bowel syndrome in primary care. Audit support. London (UK): National Institute for Health and Clinical Excellence; 2008. 12 p. (Clinical guideline; no. 61). Electronic copies: Available in Portable Document Format (PDF) from the NICE Web site.
- The guidelines manual 2007. London (UK): National Institute for Health and Clinical Excellence (NICE); 2007 April. Electronic copies: Available in Portable Document Format (PDF) from the NICE Web site.

Print copies: Available from the National Health Service (NHS) Response Line 0870 1555 455. ref: N1463. 11 Strand, London, WC2N 5HR.

PATIENT RESOURCES

The following is available:

- Irritable bowel syndrome. Understanding NICE guidance. Information for people who use NHS services. National Institute for Clinical Excellence (NICE), 2006 Jun. 15 p. Available in English and Welsh in Portable Document Format (PDF) from the National Institute for Health and Clinical Excellence (NICE) Web site.

Print copies: Available from the National Health Service (NHS) Response Line 0870 1555 455, ref: N1464. 11 Strand, London, WC2N 5HR.

Please note: This patient information is intended to provide health professionals with information to share with their patients to help them better understand their health and their diagnosed disorders. By providing access to this patient information, it is not the intention of NGC to provide specific medical advice for particular patients. Rather we urge patients and their representatives to review this material and then to consult with a licensed health professional for evaluation of treatment options suitable for them as well as for diagnosis and answers to their personal medical questions. This patient information has been derived and prepared from a guideline for health care professionals included on NGC by the authors or publishers of that original guideline. The patient information is not reviewed by NGC to establish whether or not it accurately reflects the original guideline's content.

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This summary was completed by ECRI Institute on April 9, 2009.

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